DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 28, 2015

Total Joint Orthopedics, Incorporated
Mr. Chris Weaber
Manufacturing Development Engineer
1567 East Stratford Avenue
Salt Lake City, Utah 84106

Re: K143113
Trade/Device Name: Klassic ™ BiPolar System
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWY
Dated: October 29, 2014
Received: October 30, 2014

Dear Mr. Weaber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K143113

Klassic™ BiPolar System:

Indications For Use:
The Klassic™ BiPolar System is intended for use in combination with a Total Joint Orthopedics Femoral Stem for primary or revision hemiarthroplasty of the hip, without the use of bone cement, for treatment of the following conditions:

- Femoral neck and trochanteric fractures of the proximal femur
- Osteonecrosis of the femoral head
- Revision procedures where other devices or treatments for these indications have failed.

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY

510(k) Notification K 143113

GENERAL INFORMATION

Applicant:
Total Joint Orthopedics
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Salt Lake City, UT 84106
United States
Phone: 801-486-6070
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Contact Person:
Chris Weaber
Manufacturing Development Engineer
Total Joint Orthopedics
1567 E. Stratford Avenue
Salt Lake City, UT 84106
United States
Phone: 801-486-6070
FAX: 801-486-6117

Date Prepared: October 29, 2014

DEVICE INFORMATION

Trade/Proprietary Name:
Klassic™ BiPolar System

Generic/Common Name:
Hemi-Hip prosthesis, uncemented

Classification:
21 CFR §888.3390 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis

Product Code:
KWY

510(k) SUMMARY

PREDICATE DEVICE(S)

The Klassic™ BiPolar System System is substantially equivalent in intended use, design and function to the following primary predicate device:

- BioPro Bipolar Head – BioPro (K100761)
- BioPro Bipolar Femoral Head – BioPro (K082785)

The Klassic™ BiPolar System is also substaintially equivalent in regards to technology characteristics to

- Klassic HD Hip System – Total Joint Orthopedics (K100445)
- Tandem BiPolar Hip System – Smith & Nephew (K823726)

INTENDED USE

The Klassic™ BiPolar System is intended for use in combination with a Total Joint Orthopedics Femoral Stem for primary or revision hemiarthroplasty of the hip, without the use of bone cement, for treatment of the following conditions:

- Femoral neck and trochanteric fractures of the proximal femur
- Osteonecrosis of the femoral head
- Revision procedures where other devices or treatments for these indications have failed.

PRODUCT DESCRIPTION

The Klassic™ BiPolar System includes the Klassic™ BiPolar System BiPolar Head, Klassic™ BiPolar System Femoral Head (12-14 Taper), 22mm, and Klassic™ BiPolar System Femoral Head(12-14 Taper), 28mm implant components ("Klassic™ BiPolar System Implants").

The Klassic™ BiPolar System BiPolar Head includes a factory assembled Ultra High Molecular Weight Polyethylene (UHMWPE) liner, cobalt chrome outer shell, and a UHMWPE retention ring with a Ti6Al4V spring. The Bipolar Head includes an outer diameter range from 38 to 43 mm with an inner diameter which mates with the 22 mm femoral head, and an outer diameter range from 44 to 60 mm with an inner diameter which mates with the 28mm femoral head. The Bipolar Heads are offered in 1 mm outer diameter size increments.

The Klassic™ BiPolar System Femoral Heads include a 12/14 Taper for interfacing with TJO's Klassic HD™ Femoral Stems (K100445), and TJO's Klassic HD™ Offset Femoral Stems (K133832). These heads available with offsets of Neutral, +3.5mm and +7.0mm for the 22mm Femoral Head, and -3.5, Neutral, +3.5mm and +7.0mm for the 28mm Femoral Head.

TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Klassic™ BiPolar System Implants are substantially equivalent to predicate devices. The Bipolar Head, 22mm femoral head and 28 mm femoral head feature device design, material of manufacture, sterilization and size offerings which are equivalent to predicate devices.

510(k) SUMMARY

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

Analysis for Non Clinical Testing, including fatigue, disassembly and range of motion, was completed to demonstrate that the Klassic™ BiPolar System did not create a new worst case.

All bench testing and supporting engineering evaluations demonstrate the Klassic™ BiPolar System Implants are equivalent in regards to safety and efficacy and are substantially equivalent to predicate devices.

SUBSTANTIAL EQUIVALENCE

The BiPolar Head is substantially equivalent to the predicate device, BioPro Bipolar (K100761). The indications for use for the BioPro BiPolar Head (K100761)predicate devices are substantially equivalent to the proposed indications for use for the Klassic™ BiPolar System Implants. The Klassic™ BiPolar System Implants are similar to the predicate devices based on technological characteristics, design, material, sterilization and intended use. Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the Klassic™ BiPolar System Implants are substantially equivalent to the predicate devices.